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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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U EXAMINER 16800-423

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HM12/0605

ART UNIT	PAPER NUMBER
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KISHORE, G 5

DATE MAILED: 5

06/05/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 2-114 is/are pending in the application.
- Of the above, claim(s) 2-9, 17 & 21-23 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 10-16, 18-20 & 24-114 is/are rejected.
- ☒ Claim(s) 2-9, 17 & 21-23 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

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### **DETAILED ACTION**

**The preliminary amendment filed on 12-14-00 is acknowledged.**

#### ***Claim Objections***

1. Claims 17 and 21-23 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 17 and 21-23 have not been further treated on the merits. Claims 2-9 depend from canceled claim 1 and therefore, these claims have not been further treated on the merits.

**Claims included in the prosecution are 10-16, 18-20 and 24-114.**

#### ***Claim Rejections - 35 U.S.C. § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

3. Claims 10-16, 18-20 and 24-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claims 2-9 depend from canceled claim 1.**

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4. Claims 10-13 and 24 provide for the use of the composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 10-13 and 24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

It is unclear what the treatment process is as recited in claim 14.

Proper Markush format with the expression 'selected from the group consisting of' and the use of the terms either 'and' OR 'or' only before the last Markush member should be followed in claims 15, 47, 48. What is being conveyed by "compounds containing at least one nitrogenous heterocyclic compound" in claim 15?

It is unclear what the active substance is which produces side effects as recited in claim 18. What are those side effects?

What is being conveyed by "preventing sensitive skin" as recited in claim 24 and other independent claims? Preventing from what? And what is the skin treated for?

'Side effects of dysesthesia, side effects of overheating' in claims 28 and 57 is indefinite: what are those side effects?

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**What is an allantoin sugar as recited in claims 47, 77 and 107?**

**Claim 49 recites that the P antagonist is administered together with one active ingredient that elicits an irritant side effect. Does that mean the composition in the parent claim doesn't have an irritant? Then what is the point in administering P antagonist if there is no irritant? (Also claims 79 and 109)**

**Claims 52, 82 and 112 recite application to hair and mucous membrane; this is contradictory to the parent claims which recite treatment of sensitive skin.**

#### ***Double Patenting***

**5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).**

**A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).**

**Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).**

**6. Claims 10-16, 18-20 and 24-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent**

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**No. 5,714,155. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic P substance antagonist encompasses the species claimed in the claims of said patent.**

**7. Claims 10-16, 18-20 and 24-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,679,360. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic P substance antagonist encompasses the species claimed in the claims of said patent.**

**8. Claims 10-16, 18-20 and 24-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,7888,956). Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic 'skin' in the claims of said patent includes the sensitive skin in the claims of instant application. Substance P antagonist encompasses the species claimed in the claims of said patent.**

**9. Claims 10-16, 18-20 and 24-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,824,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic claims include the administration of the irritant together with substance P antagonist as claimed in the claims of said patent. The**

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generic 'sensitive skin' in the claims of said patent includes 'sensitive but not allergic skin' in some of the claims in instant application.

10. Claims 10-16, 18-20 and 24-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,932,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the said patent recite the substance P antagonist together with other antagonists for the treatment of skin and instant claim language does not exclude the inclusion of those antagonists.

11. Claims 10-16, 18-20 and 24-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,235,291. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic P substance antagonist encompasses the species claimed in the claims of said patent.

*Claim Rejections - 35 U.S.C. § 102*

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 14-16, 25-28, 32-34, 45-46, 51-52, 55-58, 62-64, 75-76, 85-88, 97, 101, 105-106, 111, 112 and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14084.

WO teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions are in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims).

*Claim Rejections - 35 U.S.C. § 103*

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims are r 14-16, 25-28, 32-34, 45-46, 51-52, 55-58, 62-64, 75-76, 85-88, 97, 101, 105-106, 111, 112 and 114 ejected under 35 U.S.C. § 103 as being unpatentable over WO 93/14084.

As pointed out above, this publication teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as

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pruritus and urticaria. The compositions can be in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims). WO does not provide any specific examples for the topical application to the sensitive skin. However, based on the teachings of WO it would have been obvious to one of ordinary skill in the art to use the substance P antagonists taught by WO to counter the irritant side effects of a substance in the cosmetic composition due to the release of substance P since the antagonists counter the substance P.

6. Claims 10-16, 18-20 and 24-114 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact Dermatitis), Wallengren (BR. J. Dematitis) by themselves or in combination with WO 83/01252 and/or WO 93/14084 (all are of record).

Wallergren (Contact dermatitis) teaches that the substance P antagonist Spantide diminishes the contact dermatitis caused by nickel sulfate (note the abstract and page 351).

Similarly, Wallergren (Br. J) teaches the inhibiting effect of substance P antagonists against various irritants (note the entire article).

The WO publications each teach the use of substance P antagonists in medicinal preparations including topical formulations (note the entire publications).

It would thus, be obvious to one of ordinary skill in the art to prepare compositions containing substance P to combat the irritations caused by certain agents, particularly in view of the WO publications which show the use of these substances in the medicinal preparations.



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**14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

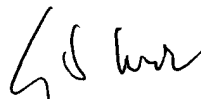
**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**June 1, 2001**